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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, *et al.*,

No. 1:23-cv-03026

Plaintiffs,

NOTICE OF SUPPLEMENTAL INFORMATION

U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

On March 28, 2023, this Court held oral argument on Plaintiff States'

Motion for Preliminary Injunction. ECF Dkt. 70. During the argument, the Court asked counsel for Defendants whether any drugs other than Mifeprex (mifepristone) are subject to a Risk Evaluation and Mitigation Strategy (REMS) that includes a pharmacy certification requirement. *See* 21 U.S.C. § 355-1(f)(3)(B). Upon further review of the REMS for approved drugs and biological products

1 posted on FDA's website,¹ Defendants have determined that more than three dozen
2 other new drug application (NDA) or biologics license application (BLA) products
3 (not including abbreviated new drug application (ANDA) products, *i.e.*,
4 "generics") are subject to a REMS that includes a pharmacy certification
5 requirement: Letairis (ambrisentan), Tracleer (bosentan), Camzyos (mavacamtem),
6 Caprelsa (vandetanib), Clozaril (clozapine), Fazacllo ODT (clozapine), Versacloz
7 (clozapine), Empaveli (pegcetacoplan), Filspari (sparsentan), Fintepla
8 (fenfluramine hydrochloride), Absorica (isotretinoin), Absorica LD (isotretinoin),
9 Juxtapid (lomitapide), Jynarque (tolvaptan), Lemtrada (alemtuzumab), Revlimid
10 (lenalidomide), Opsumit (macitentan), Myalept (metreleptin), Natpara
11 (parathyroid hormone), Palforzia (peanut (*Arachis hyogaea*) allergen powder-
12 dnfp), Palyzniq (pegvaliase-pqpz), Pomalyst (pomalidomide), Probuphine
13 (buprenorphine hydrochloride), Qsymia (phentermine and topiramate), Adempas
14 (riociguat), Siliq (brodalumab), Spravato (esketamine), Sublocade (buprenorphine
15 extended-release), Tecvalyi (teclistamab-cqyv), Tegsedi (inotersen), Thalomid
16 (thalidomide), Actiq (fentanyl citrate), Fentora (fentanyl citrate), Lazanda (fentanyl
17 citrate), Onsolis (fentanyl citrate), Subsys (fentanyl), Turalio (pexdartinib), Tysabri
18 (natalizumab), Sabril (vigabatrin), Xiaflex (collagenase clostridium histolyticum)
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¹ <https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm>

1 (for the Peyronie's disease indication), Xyrem/Xywav (calcium, magnesium,
2 potassium, and sodium oxybates), Zulresso (brexanolone), and Zyprexa Relprevv
3 (olanzapine).

5 March 29, 2023

HILARY K. PERKINS
6 Assistant Director

7 /s/ Noah T. Katzen
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17 *Counsel for Defendants*

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CERTIFICATE OF SERVICE

I hereby certify that, on March 29, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen
NOAH T. KATZEN